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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,952	03/30/2001	Charles David Claude	1225.003US1	6598

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Schwegman, Lundberg, Woessner & Kluth, P.A.
P.O. Box 2938
Minneapolis, MN 55402

EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	4

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/822,952	CLAUDE, CHARLES DAVID	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *18-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-43 are pending in the instant specification. Claims 18-43 are withdrawn from further consideration as being drawn to a non-elected species.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-17, drawn to a drug release system, classified in class 424, subclass 423.

   II. Claims 18-21, drawn to a coating, classified in class 106, subclass 14.41.

   III. Claims 22-23, drawn to method for releasing drugs, classified in class 600, subclass 891.1.

   IV. Claims 24-33, drawn to a device with implantable device, classified in class 600, subclass 890.1.

   V. Claims 34-43, drawn to method for making device, classified in class 604, subclass 523.

   The inventions are distinct, each from the other because:

   Inventions I, II, IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the products' as claimed can be made by other and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make other and

materially different products, such as a coating containing polyethylene glycol, or a coating containing poly(ethylene-co-vinyl) alcohol.

Inventions I, II, IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using can be practiced with another materially different product, such as coating, a drug release system, or device containing an implantable device.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the drug release system contain polyethylene glycol or poy(ethylene-co-vinyl)alcohol. The subcombination has separate utility such as a drug release system.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being used together, and they have different effects as invention IV contains an implantable device.

Inventions III and V are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-V, restriction for examination purposes as indicated is proper.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising a bulk polymer phase. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

2. During a telephone conversation with Janal Kalis on December 10, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-17. Election was also made to the species polyethylene glycol. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is not clear what "discrete" and "discontinuous" means in claim 2, and what "discrete" means in claim 3. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5, 10, 11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Eury et al. (U.S. Pat. No. 5,605,696).

Eury et al. relates to a drug loaded polymeric material that can be applied to a structure of an intravascular stent.

Eury teaches a polymeric material containing a therapeutically effective amount of a drug that can be combined with the structure of an intravascular stent (col. 3, lines 15-20). The drug is preferably intimately mixed with the polymeric material so as to uniformly disperse the drug in the material. The selected drug can be anticoagulant, antiplatelet, or antithrombin (col. 3, lines 60-65). The polymeric material in which the drug is incorporated can be poly(ethylene-co-vinyl acetate), poly(vinyl acetate), poly-DL-lactic acid, poly-L-actic acid, polyorthoesters, polyiminocarbonates, aliphatic polycarbonates, or polyphosphazenes (col. 4, lines 37-54).

A rate controlling membrane can also be applied over the drug loaded polymer to limit the release rate of the therapeutic drug. The rate controlling membrane can be formed to include a uniform dispersion of a porosigen in the membrane. The porosigen can be polyethylene oxide/polypropylene oxide copolymers (col. 5, lines 18-35).

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossainy et al. (U.S. Pat. No. 6,153,252).

Hossainy et al. relates to stents with coats. The coats consist of a film forming biocompatible polymer. Suitable film-forming biostable polymers with relatively low chronic tissue response, such as polyethylene glycols, can be used (col. 5, lines 6-11). The coatings can be used to deliver therapeutic and pharmaceutical agents, such as (actinomycin D) (col. 7, lines 56-62). Further, a top coating may be applied to delay release of the agent. Polymer blends may be used to control the release rate (col. 7, lines 17-18 and 25-34).

Additives may be formulated with the polymer and agent, such additives modifying the release profile. An example of such an additive is polyethylene oxide (col. 8, lines 36-51).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
December 11, 2001

NEIL S. LEVY
PRIMARY EXAMINER